201-15406

rdenison@environmentaldefense.org

06/25/2004 04:50 PM

To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, NCIC HPV@EPA, Karen Boswell/DC/USEPA/US@EPA, John_DiLoreto@americanchemistry.com
cc: MTC@mchsi.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org
Subject: Environmental Defense comments on Acetylene (CAS# 74-86-2)

(Submitted via Internet 6/25/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and John_DiLoreto@americanchemistry.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Acetylene (CAS# 74-86-2).

The Acetylene Panel of the American Chemical Council, in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted robust summaries and a test plan describing available data and proposed testing to address SIDS elements required for acetylene, also known as ethyne. Acetylene is a major industrial chemical that is, used primarily as an intermediate in the synthesis of a number of other major industrial chemicals. Current U.S. production is said by the sponsor to exceed 300 million pounds annually, most of which is said to be used as a closed-system intermediate, either at the site where it is produced or in some cases at sites to which it is sent by pipeline. Approximately 20% of total production is said to be used in acetylene torches.

The test plan submitted for acetylene provides a very good summary of background information on this chemical. Its uses and extreme volatility are said by the sponsor to limit human and environmental exposure to acetylene; however, some human exposure must occur in the course of its use, in acetylene torches. That is, even if combustion of acetylene in torches is complete, some acetylene must be released prior to combustion each time the torch is lit. Given the fact that 60 million pounds is used annually in such torches, this constitutes considerable potential for exposure.

Evidence provided indicates that acetylene's volatility will result in its partitioning almost completely to air, where it can be expected to be somewhat persistent, given the calculated photodegradation half-life of 13.1 days.

The test plan provides a thorough description of available data for acetylene and for methylacetylene, from which some data are bridged, to address some of the SIDS elements required by the HPV Challenge. Since acetylene has been a major industrial chemical for many years, some of these data are quite old, but our review indicates that most of them are satisfactory.

One general criticism of the test plan is the unwarranted frequent inference that acetylene should not be of concern because 80% is used as a closed-system intermediate. The remaining 20%, which accounts for greater than 60 million pounds annually, is used in acetylene torches that pose the potential for significant release of acetylene and direct human exposure.

Our greatest concern with the test plan is the misleading characterization

of the extent of available data presented in Table 5:

1. Table 5 indicates that "adequate" data exist for a number of endpoints where in fact there are none: This is specifically the case for the chromosome aberration and reproductive/developmental toxicity endpoints, where the text of the test plan provides a technical discussion as to why, despite the absence of data for these endpoints, testing cannot or should not be done. This proposed reliance on technical discussion to satisfy these endpoints ? not the claimed existence of adequate data -- needs to be made clear in Table 5.

2. Table 5 also needs to distinguish between where estimated/modeled vs. measured data are proposed to be used to satisfy a particular endpoint.

These types of indications have been routinely used by most other submitters in their test plan summary tables, and the sponsor should consult other examples and revise Table 5 to accurately summarize its proposed approach to satisfy each SIDS endpoint.

Other comments follow:

3. Ecotoxicity: While we consider the estimated data provided to satisfy these endpoints to be sufficient, for the record we must take exception with the test plan's claim that studies of the ecotoxicity endpoints are not relevant due to the volatility of acetylene. The Challenge program provides no such exemption for gases, and approved methods applicable to gases exist for testing for these endpoints. The existence of the (admittedly poorly documented) studies the sponsor cites in Table 3 demonstrates such tests can be ? and have been -- conducted. Moreover, the measured values reported in these studies suggest some potential aquatic toxicity at least under test conditions. Arguments made by the sponsor that acetylene is too volatile to be present in aquatic environments do not suffice to obviate the need to provide data or technical discussion to satisfy these endpoints. Such arguments go beyond hazard determination to encompass exposure and risk considerations that are beyond the scope of this program. Finally the claim made by the sponsor that the hazards posed by such testing "is not worth the risks" is presumably a reference to the flammability and explosivity of acetylene at high concentrations; but would achieving the concentrations of acetylene in water at which toxicity has been estimated or observed to occur, all of which are well below the lower explosive level (LEL) of 25,000 ppm, require its presence in air at concentrations above the LEL? (We recognize that, given its volatility, acetylene is not going to remain in water unless there is an appreciable concentration in the air above the water.)

4. Repeat dose toxicity: In discussing data summarized in Table 4, the test plan states: "The rats, rabbits, guinea pigs and dogs generally recovered from narcosis in a short time. However, the mice did not survive treatment." The actual data indicate otherwise for rats, rabbits, guinea pigs and dogs, where many animals died even at the lower doses administered. While it is not clear ? because data are not presented ? whether similar rates of death occurred in the control group, the statement that "the rats, rabbits, guinea pigs and dogs generally recovered" is clearly not accurate. The data presented also appear rather inconsistent,

as significant numbers of deaths were observed for rats and guinea pigs at 25,000 ppm and no deaths were observed at 80,000 ppm. We are not, however, suggesting that further testing for this endpoint is needed.

5. We would question most aspects of the rationale provided by the sponsor for not testing for chromosome aberration. The argument that testing is not needed because of claimed low exposure is not relevant to the hazard determination purpose of the Challenge program, and at any rate determination of whether exposure is accurately characterized as "low" is dependent on the actual level of exposure shown either to cause or not to result in chromosome aberrations.

6. In the absence of any actual test data, how does the sponsor know that "meaningful concentrations" would necessarily exceed the 25,000 ppm LEL level that would be needed to pose a "high fire and explosion concentration"?

7. A minor error in this section of the test plan is the listing of a rationale for not testing for reproductive toxicity in the first bullet under 4.4.3.2, which addresses chromosomal aberration.

8. Again for reproductive/developmental toxicity endpoints, the sponsor claims that "meaningful concentrations" would necessarily exceed the 25,000 ppm LEL level that would be needed to pose a "high fire and explosion concentration." The test plan further states: "Reproductive and developmental testing would require inhalation chambers that contained greater than the lower explosive limit concentration (25,000 ppm) of acetylene in order to demonstrate a toxicological effect." On what basis are these claims made that testing at levels below the LEL would not be "meaningful"? Why can't the sponsor test this chemical in the manner used in other cases with explosive chemicals, i.e., at levels approaching, but less than, those known to be explosive?

9. Invoking the "history, nature and uses" of a chemical to justify not testing ? as the sponsor does throughout the test plan ? is inconsistent with the purpose of the Challenge program, which is hazard ? not exposure or risk ? assessment.

10. We appreciate the inclusion in the test plan and robust summaries of summaries of additional information, e.g., human toxicity and metabolism studies as well as epidemiology studies, not required by the HPV Challenge.

In summary, the sponsor has not yet made a fully convincing case for why the limited available data are sufficient to satisfy all of the SIDS requirements under the HPV Challenge. The rationales provided for not testing for those endpoints with no or inadequate data suffer from some deficiencies that need to be addressed in revising this submission for it to be considered an acceptable response to the HPV Challenge.

Thank you for this opportunity to comment.

Hazel B. Matthews, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense